PMA Monthly approvals from 8/1/2016 to 8/31/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150001	08/10/2016	PMAO - PMA Origi	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for the MiniMed 630G System with SmartGuard.
P150036	08/12/2016	PMAO - PMA Origi	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCE S, LLC.	Approval for the EDWARDS INTUITY Elite Valve System. This device is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S082	08/10/2016	S - Special CBE	VISTAKON(ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Approval for labeling modifications to the device.
P890003/S360	08/11/2016	R - Real-Time Proc	MEDTRONIC CARELINK ENCORE 29901 PROGRAMMER	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updated hardware components, minor mechanical changes, and corresponding software updates to the computing platform.
P910001/S079	08/31/2016	N - Normal 180 Day	ELCA CORONARY ATHERECTOMY CATHETERS	SPECTRANETI CS CORP.	Approval for a substitution of the SpectraGlide hydrophilic coating for the TreeFrog hydrophilic coating on the ELCA catheters.

Data as of 09/06/2016 03:48 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S175	08/24/2016	N - Normal 180 Day	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Approval for the expansion of MRI conditional labeling for the Amplia MRI and Compia MRI Systems to include 3T MRI.
P930014/S091	08/05/2016	R - Real-Time Proc	ACRYSOF IQ TORIC IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for AcrySof® IQ Toric IOL with the UltraSert Pre-Loaded Delivery System, Models AU00T3, AU00T4, AU00T5, AU00T6, AU00T7, AU00T8 and AU00T9.
P930039/S148	08/24/2016	N - Normal 180 Day	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for the expansion of MRI conditional labeling for the Amplia MRI and Compia MRI Systems to include 3T MRI.
P950020/S072	08/18/2016	N - Normal 180 Day	WOLVERINE CORONARY CUTTING BALLOON (MONORAIL & OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Approval for updates to the atherotomes, adhesive, balloon catheter platform, device packaging and the sterilization process. The device, as modified, will be marketed under the trade name WOLVERINE Coronary Cutting Balloon (Monorail & Over-The-Wire) and is indicated for dilatation of stenoses in coronary arteries for the purpose of improving myocardial perfusion in those circumstances where a high pressure balloon resistant lesion is encountered. In addition, the target lesion should possess the following characteristics: Discrete (<15 mm in length), or tubular (10 mm to 20 mm in length); Reference Vessel Diameter (RVD) of 2.00 mm to 4.00 mm; Readily accessible to the device; Light to moderate tortuosity of proximal vessel segment; Non-angulated lesion segment (<45 Degrees); Smooth angiographic contour; Absence of angiographically visible thrombus and/or calcification.
P960016/S064	08/02/2016	Y - 135 Review Tra	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	St. Jude Medical	Approval to rework the catheter electrode-rings at two different time points in the manufacturing process workflow.
P960040/S376	08/19/2016	R - Real-Time Proc	DYNAGEN EL & MINI, INOGEN EL & MINI, ORIGEN EL & MINI IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for a change to the acceptance criteria for a molded component.
P960053/S005	08/09/2016	S - Special CBE	BRAUN-CUTTER TRAPEZO-METACARPAL PROSTHESIS	STRYKER CORPORATIO N	Approval of changes to the device labeling.
P970003/S202	08/12/2016	S - Special CBE	VNS THERAPY ASPRICE HC AND ASPIRESR, DEMIPULSE AND DEMIPULSE DUO, PULSE AND PULSE DUO GENERATORS; VNS THERAPY PERENNIADURA AND PERENNIAFLEX LEADS, THERAPY LEAD.	CYBERONICS, INC.	Approval for labeling changes to address adverse events (AE) associated with the VNS stimulation following electrical cardioversion procedures.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S218	08/24/2016	O - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for a manufacturing site for kitting operations.
P970004/S221	08/05/2016	S - Special CBE	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for changes to the labeling to correct and modify instructions regarding the use of the cycling feature and its impact on battery longevity.
P970029/S032	08/23/2016	S - Special CBE	CARDIOGENESIS TMR LASER SYSTEM	CRYOLIFE, INC.	Approval for labeling changes to enhance the safety of CardioGenesis® TMR Laser System.
P970051/S144	08/23/2016	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the new MP3000 cochlear implant digital sound coding strategy.
P980016/S592	08/07/2016	N - Normal 180 Day	GEM II DR/GEM II VR/GEM III DR/GEM III VR/ENTRUST/ INTRINSIC 30/INTRINSIC/ MARQUIS DR/MARQUIS VR/ MAXIMO II DR/MAXIMO II/ MAXIMO VR/PROTECTA/ PROTECTA XT/SECURA/ VIRTUOSO/VIRTUOSO II DR/VR ICDS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a web-based battery longevity estimation tool for ICD and CRT-D devices and updates to the existing battery longevity estimation tools.
P980040/S066	08/16/2016	N - Normal 180 Day	TECNIS TORIC CALCULATOR	ABBOTT MEDICAL OPTICS INC	Approval for a software update to your TECNIS® Toric Calculator to include the following: 1) Prospective addition of the FDA-approved ZCT375 I0OL); and 2) Incorporation of an optional feature to add the posterior corneal astigmatism (PCA) factor into the toric lens calculation.
P980050/S104	08/07/2016	N - Normal 180 Day	GEM III AT ICD	MEDTRONIC INC.	Approval for a web-based battery longevity estimation tool for ICD and CRT-D devices and updates to the existing battery longevity estimation tools.
P990012/S024	08/08/2016	Y - 135 Review Tra	ELECSYS HBSAG IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P990071/S033	08/04/2016	N - Normal 180 Day	SMARTABLATE SYSTEM: SMARTABLATE RF GENERATOR AND REMOTE CONTROL, SMARTABLATE SYSTEM: SMARTABLATE IRRIGATION PUMP	BIOSENSE WEBSTER, INC.	Approval to implement hardware and software updates to the SmartAblate System - RF Generator and Remote Control and Irrigation Pump.
P000053/S065	08/30/2016	R - Real-Time Proc	AMS 800 URINARY CONTROL SYSTEM WITH INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Approval for changes to design documentation for the cuff assembly, pressure regulating balloon, and control pump.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S423	08/23/2016	N - Normal 180 Day	ACUITY X4 STRAIGHT, ACUITY X4 SPIRAL S, ACUITY X4 SPIRAL L QUADRIPOLAR CORONARY VENOUS PACE/SENSE LEADS	BOSTON SCIENTIFIC CORP.	Approval for modifications to the terminal connector.
P010012/S427	08/19/2016	R - Real-Time Proc	DYNAGEN & X4, INOGEN & X4, ORIGEN & X4 CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR	BOSTON SCIENTIFIC CORP.	Approval for a change to the acceptance criteria for a molded component.
P010031/S538	08/24/2016	N - Normal 180 Day	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for the expansion of MRI conditional labeling for the Amplia MRI and Compia MRI Systems to include 3T MRI.
P010031/S553	08/07/2016	N - Normal 180 Day	CONCERTO/CONCERTO II/ CONSULTA DF4/ CONSULTA/INSYNC II PROTECT/INSYNC III MARQUIS/INSYNC MAXIMO/INSYNC SENTRY/ INSYNC II MARQUIS/ INSYNC MARQUIS/MAXIMO II/PROTECTA/PROTECTA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a web-based battery longevity estimation tool for ICD and CRT-D devices and updates to the existing battery longevity estimation tools.
P010054/S026	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HBS IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P020045/S073	08/31/2016	P - Panel Track	FREEZOR XTRA SURGICAL CARDIAC CRYOABLATION DEVICE	MEDTRONIC CRYOCATH LP	Approval for the Freezor Xtra Cardiac CryoAblation Catheter, CryoConsole system, and related accessories. The device is indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT). The Freezor Xtra catheter is also intended for minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The Freezor Xtra catheter freezes the target tissue and blocks the electrical conduction by creating an inflammatory response or cryonecrosis.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020056/S032	08/25/2016	O - Normal 180 Day	NATRELLE SILICONE-FILLED BREAST IMPLANTS.	ALLERGAN	Approval for removal of the DSMB from the BIFS-001 study protocol.
P030017/S241	08/16/2016	N - Normal 180 Day	PRECISION SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for minor design changes to the Precision OR Cable and Extension used with the Precision SCS system, to be procured from alternate qualified supplier Onanon Inc. at Milpitas, California.
P030031/S072	08/11/2016	N - Normal 180 Day	THERMOCOOL SMARTTOUCH SF UNI-DIRECTIONAL NAVIGATION CATHETER; THERMOCOOL SMARTTOUCH SF BI-DIRECTIONAL NAVIGATION CATHETE	BIOSENSE WEBSTER, INC.	Approval for the THERMOCOOL SMARTTOUCH® SF Catheters, part numbers D-1347-XX-S and D-1348-XX-S, indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used with a compatible RF generator, for the treatment of: 1) Type I atrial flutter in patients age 18 or older; and 2) Drug refractory recurrent symptomatic paroxysmalatrial fibrillation, when used with compatible three dimensional electroanatomic mapping systems. The THERMOCOOL SMARTTOUCH® SF Navigation Catheter provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO® 3 Navigation System.
P040003/S018	08/26/2016	R - Real-Time Proc	EXABLATE 2000 SYSTEM	INSIGHTEC, LTD	Approval for change to the ExAblate system to comply with the European directive 2002/95/EC and 2011/65/EU in relation to Restriction of Hazardous Substance (RoHS).
P040004/S012	08/11/2016	N - Normal 180 Day	ADVIA CENTAUR HBC TOTAL ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur® HBc Total Assay (ADVIA Centaur® HBc Total ReadyPack Reagents and ADVIA Centaur® HBc Total Quality Control Materials) to the ADVIA Centaur® XPT system.
P040021/S028	08/01/2016	O - Normal 180 Day	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	Approval for a final labeling update.
P040027/S048	08/18/2016	N - Normal 180 Day	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Approval for addition of GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion to the GORE® VIATORR® TIPS Endoprosthesis product line.
P040046/S014	08/25/2016	O - Normal 180 Day	NATRELLE HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for removal of the DSMB from the BIFS-001 study protocol.
P040046/S016	08/17/2016	R - Real-Time Proc	NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for changes to the presentation format of the indication-specific brochures and mini-brochure.
P050023/S100	08/01/2016	O - Normal 180 Day	PROMRI ICD/CRT-D SYSTEM	BIOTRONIK, INC.	Approval of the post-approval study protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060006/S075	08/11/2016	O - Normal 180 Day	EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific, 2 Scimed Place, Maple Grove, Minnesota, for stent finishing, inspection, and cleaning.
P070014/S051	08/31/2016	O - Normal 180 Day	BARD LIFESTENT VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval of the post-approval study protocol.
P080006/S089	08/24/2016	N - Normal 180 Day	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Approval for the expansion of MRI conditional labeling for the Amplia MRI and Compia MRI Systems to include 3T MRI.
P080025/S113	08/24/2016	O - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR BOWEL	MEDTRONIC NEUROMODULATION	Approval for a manufacturing site for kitting operations.
P080025/S116	08/05/2016	S - Special CBE	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM FOR BOWEL	MEDTRONIC NEUROMODULATION	Approval for changes to the labeling to correct and modify instructions regarding the use of the cycling feature and its impact on battery longevity.
P090003/S042	08/11/2016	O - Normal 180 Day	EXPRESS LD ILIAC OVER-THE-WIRE PREMOUNTED STENT SYSTEM	Boston Scientific Corporation	Approval for a manufacturing site located at Boston Scientific, 2 Scimed Place, Maple Grove, Minnesota, for stent finishing, inspection, and cleaning.
P090012/S011	08/18/2016	N - Normal 180 Day	MELAFIND	STRATA SKIN SCIENCES, INC.	Approval for changing your calibration validation self-test method from the Field Phantom Imaging Self-Test to the Flap Shutter Self-Test.
P090013/S220	08/24/2016	N - Normal 180 Day	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Approval for the expansion of MRI conditional labeling for the Amplia MRI and Compia MRI Systems to include 3T MRI.
P090018/S031	08/01/2016	O - Normal 180 Day	ESTEEM	ENVOY MEDICAL CORPORATION	Approval for modification of the approved labeling for the Esteem to reflect the findings of the Post-Approval Study protocol.
P100009/S018	08/09/2016	R - Real-Time Proc	MITRACLIP CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval for a design change to the Actuator Slider component of the delivery system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100010/S058	08/31/2016	O - Normal 180 Day	ARCTIC FRONT CARDIAC CRYOABLATION SYSTEM: 23MM AND 28MM ARCTIC FRONT CATHETERS, FREEZOR MAX CATHETER, CRYOCONSOLE, MANUAL RETRACTION KIT AND ACCESSORIES	MEDTRONIC CRYOCATH LP	Approval of the following changes to the post-approval study for the device: reduce the follow-up period from 5 years to 3 years and terminate the study after all subjects have had 3 years of follow-up and the primary endpoint has been reached.
P100031/S014	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HBC IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P100032/S011	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HBC IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P100039/S004	08/20/2016	N - Normal 180 Day	ADVIA CENTAUR ANTI HBS2 ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur® Anti-HBs2 (aHBs2) Assay and ADVIA Centaur® Anti-HBs2 (aHBs2) Quality Control Material to the ADVIA Centaur® XPT system.
P110008/S005	08/23/2016	O - Normal 180 Day	COFLEX® INTERLAMINAR TECHNOLOGY	PARADIGM SPINE, LLC	Approval for the manufacturing sites located at 6688 Dixie Highway, Bridgeport, MI 48722 for the packaging and labeling of the coflex Interlaminar Technology; 11911 Clark Street, Arcadia, CA 91006 for the laser marking, in-process cleaning, and inspection of the coflex Interlaminar Technology; and 1880 Industrial Drive, Libertyville, IL 60048 for the sterilization of the coflex Interlaminar Technology.
P110022/S015	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HBC IGM IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P110025/S013	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HBC IGM IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P110031/S012	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HBC IGM IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P110035/S036	08/11/2016	O - Normal 180 Day	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific, 2 Scimed Place, Maple Grove, Minnesota, for stent finishing, inspection, and cleaning.
P110039/S006	08/26/2016	R - Real-Time Proc	EXABLATE	INSIGHTEC	Approval for change to the ExAblate system to comply with the European directive 2002/95/EC and 2011/65/EU in relation to Restriction of Hazardous Substance (RoHS).
P110042/S058	08/08/2016	N - Normal 180 Day	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	Boston Scientific Corporation	Approval for the Model A219 EMBLEM MRI S-ICD as well as modifications to the Model A209 EMBLEM S-ICD, Model 3401 EMBLEM S-ICD Subcutaneous Electrode, Model 4711 EMBLEM S-ICD Subcutaneous Electrode Insertion Tool, Model 2877 Programmer Software Application and Model 3200 EMBLEM S-ICD Programmer.
P110042/S060	08/19/2016	R - Real-Time Proc	EMBLEM SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	Boston Scientific Corporation	Approval for a change to the acceptance criteria for a molded component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120005/S048	08/02/2016	R - Real-Time Proc	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for firmware changes to the Dexcom G5 Mobile Receiver to decrease occurrence of certain recoverable errors requiring a system reset. In addition, the firmware changes address customer complaints related to the recoverable errors. The Dexcom G5 Mobile Receiver is a component of the Dexcom G5® Mobile Continuous Glucose Monitoring System.
P120016/S020	08/01/2016	R - Real-Time Proc	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Approval for a change to the material of the Joiner component of the VASCADE 6/7F Sleeve with Grip subassembly.
P130009/S057	08/18/2016	P - Panel Track	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards SAPIEN XT Transcatheter Heart Valve and accessories for expanding the indication to include patients with intermediate surgical risk for aortic valve replacement. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >= 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
P130009/S061	08/02/2016	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval of the following changes to the post-approval study for the device: minor editorial changes and updates to contact information.
P130009/S062	08/19/2016	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Approval for various changes to the post-approval study protocol for the continued follow-up of the IDE Nested Registry #3.
P130013/S009	08/04/2016	O - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corporation, Maple Grove Facility located at One Scimed Place, Maple Grove, Minnesota, 55311 as an additional manufacturing site for the Watchman Closure Device with Delivery System.
P130014/S002	08/02/2016	N - Normal 180 Day	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Approval for changes in a nozzle design and packaging of the Adherus Autospray ET (Extended Tip) Dural Sealant.
P130015/S005	08/08/2016	Y - 135 Review Tra	ELECSYS HBEAG IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P130016/S017	08/23/2016	N - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the new MP3000 cochlear implant digital sound coding strategy.
P130017/S010	08/19/2016	R - Real-Time Proc	COLOGUARD	EXACT SCIENCES CORPORATION	Approval for design changes to Cologuard Collection Kit and associated patient labeling.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130021/S022	08/26/2016	R - Real-Time Proc	MEDTRONIC COREVALVE (R) EVOLUT R SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifying the dimensions of the screw gear component.
P130021/S024	08/22/2016	S - Special CBE	COREVALVE (TM) EVOLUTE (TM) R SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifications to the CoreValve Evolut R System Instructions for Use.
P130029/S004	08/24/2016	O - Normal 180 Day	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Approval for a manufacturing site located at Sterigenics Belgium Petit-Rechain S.A., Zoning Industriel de petit-Rechain, Avenue Andre Ernst 21, Petit-Rechain, Verviers, 4800, Belgium, for contract sterilization.
P140003/S009	08/09/2016	O - Normal 180 Day	IMPELLA VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Approval of the post-approval study protocol.
P140003/S010	08/09/2016	O - Normal 180 Day	IMPELLA VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Approval of the post-approval study protocol.
P140013/S002	08/30/2016	O - Normal 180 Day	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for a manufacturing site located at Minnetronix, Inc., 1635 Energy Park, Saint Paul, Minnesota, as a new manufacturing facility.
P140021/S003	08/08/2016	Y - 135 Review Tra	ELECSYS ANTI-HCV II IMMUNOASSAY	ROCHE DIAGNOSTICS	Approval for changes to the final kit packaging configuration, modifications to an existing packaging line, and addition of two new packaging lines.
P140031/S010	08/18/2016	P - Panel Track	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the SAPIEN 3 Transcatheter Heart Valve and accessories for expanding the indication to include patients with intermediate surgical risk for aortic valve replacement. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >= 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
P140031/S015	08/19/2016	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for various changes to the post-approval study protocol for the continued follow-up of the IDE High Risk Patients Cohort.
P150003/S006	08/17/2016	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Approval for changes to the gradient outers and manifold component of the delivery system.
P150023/S002	08/25/2016	S - Special CBE	ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for labeling changes to clarify the interpretation of the ABSORB III clinical data for geriatric patients in the Absorb GT1 BVS Instructions for Use.

Total: 80

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16895/S098	08/12/2016	X - 30-Day Notice	SOFLENS (POLYMACON) VISIBILITY TINTED CONTACT LENSES	BAUSCH & LOMB, INC.	Relocation of twelve manufacturing lines.
N18033/S083	08/08/2016	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Implement changes to the method of adjusting the monomer dose level target of the monomer dose system for the VISTAKON® (etafilcon A) Brand Contact Lenses.
N970003/S191	08/02/2016	X - 30-Day Notice	ESSENTIO, PROPONENT, ACCOLADE,ALTRUA 2 PACEMAKER'S	BOSTON SCIENTIFIC CORP.	Changes to the molding manufacturing line.
N970003/S192	08/10/2016	X - 30-Day Notice	ALTRUA, ESSENTIO, PROPONENT, ACCOLADE PACEMAKERS	BOSTON SCIENTIFIC CORP.	Changes to an acceptance limit and sampling rate during battery testing.
N970012/S117	08/03/2016	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) WITH INHIBIZONE	BOSTON SCIENTIFIC CORP.	Quality control changes related to InhibiZone formulation including reduction of test samples, change in detection method from HPLC to UPLC, and change in facility conducting test.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P800036/S039	08/29/2016	X - 30-Day Notice	MODEL 400 IMPLANTABLE INFUSION PUMP	CODMAN & SHURTLEFF, INC.	Approval for modifications associated with accessories for P800036 and P890055: Needles: needle drawing changes and process control improvements at the supplier; and Luer adaptor: supplier manufacturing site changes.
P810032/S066	08/11/2016	X - 30-Day Notice	MULTI-PIECE POSTERIOR CHAMBER IOL	ALCON LABORATORIES	Change in aeration time after EO sterilization for PMMA IOLs and for AcrySof® Posterior Chamber Intraocular Lens with UltraSert Preloaded Delivery System at the Huntington AODC manufacturing facility.
P840001/S336	08/18/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS 977C165, 977C190, 977C265, 977C290	MEDTRONIC NEUROMODULATION	Implementation of select repackaging and relabeling activities on Spinal Cord Stimulation MRI Surgical leads that are returned to Medtronics Memphis Distribution Center.
P840001/S337	08/22/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Changes to the manufacturing execution system (FACTORYworks) for Business Rule Client 9.2, Configuration Client 9.2, and Integrated Manufacturing Process Management Web Services 3.1.0.
P840001/S338	08/25/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATIONS LEADS	MEDTRONIC NEUROMODULATION	Addition of a new supplier of polysulfone resin.
P840001/S339	08/31/2016	X - 30-Day Notice	RESTORE, ITREL SPINAL CORD STIMULATION SYSTEMS	MEDTRONIC NEUROMODULATION	Alternate printed wiring board for use in hybrid manufacturing.
P840060/S043	08/11/2016	X - 30-Day Notice	SINGLE-PIECE POSTERIOR CHAMBER IOL	ALCON LABORATORIES	Change in aeration time after EO sterilization for PMMA IOLs and for AcrySof® Posterior Chamber Intraocular Lens with UltraSert Preloaded Delivery System at the Huntington AODC manufacturing facility.
P850048/S042	08/26/2016	X - 30-Day Notice	ACCESS PSA REAGENTS ON THE ACCESS IMMUNOASSAY ANALYZER	BECKMAN COULTER, INC.	Manufacturing process change to use PSA reference calibrators instead of commercial calibrators to establish a valid calibration curve during the in-process qualification of the coated PSA paramagnetic particles.
P850064/S033	08/18/2016	X - 30-Day Notice	LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Change to the Ultrasonic Welding Process used in fabrication of the Cartridge of the Patient Circuit.

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P860004/S258	08/22/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Changes to the manufacturing execution system (FACTORYworks) for Business Rule Client 9.2, Configuration Client 9.2, and Integrated Manufacturing Process Management Web Services 3.1.0.
P860004/S259	08/31/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Alternate printed wiring board for use in hybrid manufacturing.
P880086/S274	08/19/2016	X - 30-Day Notice	ASSURITY - PM1240, PM2240, ASSURITY+ - PM1260, PM2260, ENDURITY - PM1160, PM2160, ENDURITY CORE - PM1152, PM2152	ST. JUDE MEDICAL, INC.	Alternate supplier of pacemaker case halves.
P880087/S025	08/11/2016	X - 30-Day Notice	SINGLE-PIECE ANTERIOR CHAMBER IOL	ALCON LABORATORIES	Change in aeration time after EO sterilization for PMMA IOLs and for AcrySof® Posterior Chamber Intraocular Lens with UltraSert Preloaded Delivery System at the Huntington AODC manufacturing facility.
P890003/S362	08/10/2016	X - 30-Day Notice	MYCARELINK PATIENT MONITOR, MYCARELINK READER FIELD REPLACEMENT UNIT (FRU), MYCARELINK SMART PATIENT READER, CARELINK ENCORE PROGRAMMER, CARELINK ENORE PROGRAMMER HEAD, CARELINK EXPRESS MONITOR, MEDTRONIC CARELINK MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the final assembly process for monitors and programmers.
P890055/S063	08/18/2016	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION SYSTEM	CODMAN	Move downstream manufacturing processes from the Medos International facility located at Chemin Blanc, Le Locle, Switzerland to Codman Neuro Sciences located at Rue Girardet, Le Locle, Switzerland.
P890055/S064	08/29/2016	X - 30-Day Notice	CODMAN 3000 SERIES CONSTANT-FLOW IMPLANTABLE INFUSION PUMP AND MEDSTREAM IMPLANTABLE INFUSION PUMP	CODMAN	Approval for modifications associated with accessories for P800036 and P890055: Needles: needle drawing changes and process control improvements at the supplier; and Luer adaptor: supplier manufacturing site changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900033/S055	08/22/2016	X - 30-Day Notice	INTEGRA ARTIFICIAL SKIN & MESHED DERMAL REGENERATION TEMPLATE,INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX, INTEGRA MESHED DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Implementation of upgraded equipment and software for pore size analysis.
P900056/S154	08/10/2016	X - 30-Day Notice	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P910073/S137	08/02/2016	X - 30-Day Notice	ENDOTAK RELIANCE 4-SITE LEADS PASSIVE FIXATION & ENDOTAK RELIANCE 4-SITE ACTIVE FIXATION	BOSTON SCIENTIFIC	Changes to the molding manufacturing line.
P910073/S139	08/22/2016	X - 30-Day Notice	ENDOTAK RELIANCE G/SG DEFIBRILLATION LEADS AND G/SG WITH 4-SITE CONNECTOR DEFIBRILLATION LEADS	BOSTON SCIENTIFIC	Addition of a pull test process monitoring step.
P920047/S094	08/11/2016	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P930014/S093	08/12/2016	X - 30-Day Notice	ACRYSOF INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Reduction in Plan View Final Dimensional Inspection from 100% to sampling for all AcrySof Single-Piece, non-toric IOL models.
P930014/S095	08/11/2016	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENS WITH ULTRASERT PRELOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Change in aeration time after EO sterilization for PMMA IOLs and for AcrySof® Posterior Chamber Intraocular Lens with UltraSert Preloaded Delivery System at the Huntington AODC manufacturing facility.
P930031/S056	08/24/2016	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS (TIPS)	BOSTON SCIENTIFIC CORP.	Outsourcing the compounding process for numerous resins.

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P930039/S154	08/22/2016	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional laser welding equipment.
P940019/S047	08/24/2016	X - 30-Day Notice	WALLSTENT ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Outsourcing the compounding process for numerous resins.
P950027/S015	08/26/2016	X - 30-Day Notice	HYALGAN	FIDIA FARMACEUTICI SPA	Change in the filter cartridge used during manufacturing of Hyalgan.
P960004/S077	08/02/2016	X - 30-Day Notice	FINELINE II	BOSTON SCIENTIFIC	Changes to the molding manufacturing line.
P960009/S258	08/22/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Changes to the manufacturing execution system (FACTORYworks) for Business Rule Client 9.2, Configuration Client 9.2, and Integrated Manufacturing Process Management Web Services 3.1.0.
P960009/S259	08/25/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of a new supplier of polysulfone resin.
P960009/S260	08/31/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Alternate printed wiring board for use in hybrid manufacturing.
P960040/S377	08/02/2016	X - 30-Day Notice	DYNAGEN, INOGEN, ORIGEN ICD'S	BOSTON SCIENTIFIC	Changes to the molding manufacturing line.
P960040/S378	08/01/2016	X - 30-Day Notice	DYNAGEN EL ICD: D150, D151, D152, D153; INOGEN EL ICD: D140, D141, D142, D143; ORIGEN EL ICD: D050, D051, D052, D053;	BOSTON SCIENTIFIC	Alternate supplier of the titanium raw material used for capacitor can manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970003/S203	08/12/2016	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Addition of an alternate automated proofreading system for receiving inspection of printed labeling materials at the Houston manufacturing facility.
P970004/S222	08/22/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Changes to the manufacturing execution system (FACTORYworks) for Business Rule Client 9.2, Configuration Client 9.2, and Integrated Manufacturing Process Management Web Services 3.1.0.
P970004/S223	08/31/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Alternate printed wiring board for use in hybrid manufacturing.
P970037/S009	08/23/2016	X - 30-Day Notice	AUTODELFIA HAFP TEST SYSTEM	PERKINELMER, INC.	Modification of two of the incoming quality control test methods performed for the bovine serum albumin (BSA) raw material and Change of the environmental ISO classification.
P970051/S149	08/24/2016	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an alternate PCB supplier for sound processor coils.
P980003/S068	08/11/2016	X - 30-Day Notice	CHILLI COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P980003/S069	08/19/2016	X - 30-Day Notice	CHILLI II	BOSTON SCIENTIFIC CORP.	Addition of alternate vendors for manufacturing components for the Chilli II, Blazer OI, and IntellaNav OI Temperature Ablation Catheters.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S597	08/16/2016	X - 30-Day Notice	EVERA MRI ICD DDMB1D4, DDMC3D4, DVMB1D4, DVMC3D4; EVERA S DR ICD DDBC3D1, DDBC3D4; EVERA S VR ICD DVBC3D1, DVBC3D4; EVERA XT DR ICD DDBB1D1, DDBB1D4; EVERA XT VR ICD DVBB1D1, DVBB1D4; MAXIMO II ICD D264DRM, D264VRM, D284VRC, D284DRG; PROTECTA ICD D334DRG, D334VRG, D334DRM; PROTECTA VR ICD D334VRM; PROTECTA XT ICD D314DRG, D314VRG, D314DRM, D314VRM; SECURA DR ICD D224DRG, D204DRM, D204VRM, D224VRC; VIRTUOSO II DR/VR ICD D274DRG, D274VRC; VISIA AF MRI VR ICD DVFB1D4, DVFC3D4; VISIA AF VR ICD DVAB1D1, DVAB1D4, DVAC3D1, DVAC3D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks 9.2 at the Medtronic Tempe Campus.
P980022/S193	08/25/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL INSULIN PUMP & PARADIGM REAL-TIME INSULIN PUMP.	MEDTRONIC MINIMED	Add a new testing station to conduct a Manual Bolus Time Test (BTT) in the manufacturing process of the Paradigm Real-Time Insulin Pumps, Paradigm Real-Time Revel Pumps, and MiniMed 530G Insulin Pumps. These pumps are components of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and MiniMed 530G System, respectively. The testing station will be added to the manufacturing facility, located at Juncos, Puerto Rico.
P980023/S077	08/22/2016	X - 30-Day Notice	PROTEGO SD 60/16, PROTEGO SD 65/16, PROTEGO SD 65/18, PROTEGO SD 75/18, PROTEGO TD 65/16, PROTEGO TD 65/18, PROTEGO TD 75/18, PROTEGO S 60, PROTEGO S 65, PROTEGO S 75, PROTEGO T 65	BIOTRONIK, INC.	Addition of an alternate supplier for the DF4 connector.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980033/S045	08/24/2016	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS (VENOUS)	Boston Scientific Corporation	Outsourcing the compounding process for numerous resins.
P980035/S472	08/16/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1, SEDR01, SESR01, VEDR01, ADD01, SEDRL1, SED01, SES01, ADSR01, ADSR03, ADSR06, ADVDD01; ADVISA DR IPG A4DR01; ADVISA DR MRI IPG A2DR01; ADVISA SR MRI IPG A3SR01; RELIA IPG RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks 9.2 at the Medtronic Tempe Campus.
P980037/S058	08/18/2016	X - 30-Day Notice	ANGIOJET ULTRA XMI, SPIROFLEX, SPIROFLEX VG, DISTAFLEX THROMBECTOMY SET'S	BOSTON SCIENTIFIC CORP.	Manufacturing changes to the Angiojet production line.
P980049/S115	08/09/2016	X - 30-Day Notice	PLATINIUM VR 1210/1240, PLATINIUM DR 1510/1540 (ICD)	SORIN GROUP- CRM	Add a second sterilizer for Platinium devices.
P980049/S116	08/08/2016	X - 30-Day Notice	PLATINIUM VR 1210; PLATINIUM VR 1240; PLATINIUM DR 1510; PLATINIUM DR 1540	SORIN GROUP- CRM	Use of the Automated Optical Inspection equipment during the microelectronic and electronic assembly manufacturing.
P990046/S047	08/04/2016	X - 30-Day Notice	OPEN PIVOT HEART VALVE & OPEN PIVOT AORTIC VALVED GRAFT	MEDTRONIC ATS MEDICAL, INC.	Update to software used in the manufacturing process for the Open Pivot Heart Valve and Aortic Valved Graft.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000012/S056	08/04/2016	X - 30-Day Notice	COBAS AMPLICOR HCV	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.
P000021/S029	08/30/2016	X - 30-Day Notice	DIMENSION TPSA FLEX REAGENT CARTRIDGE (RF451)	SIEMENS HEALTHCARE DIAGNOSTICS	Add a filtration step in the Chrome Particle Raw Material (CPRM) manufacturing process.
P000039/S056	08/04/2016	X - 30-Day Notice	AMPLATZER SEPTAL OCCLUDER AND AMPLATZER MULTI-FENESTRATED SEPTAL OCCLUDER	AGA MEDICAL CORP.	Change to the pre-sterilization bioburden action and alert levels.
P000053/S066	08/03/2016	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH INHIBIZONE	BOSTON SCIENTIFIC CORP.	Quality control changes related to InhibiZone formulation including reduction of test samples, change in detection method from HPLC to UPLC, and change in facility conducting test.
P000058/S061	08/11/2016	X - 30-Day Notice	LT-CAGE LUMBAR TAPERED/INTER FIX THREADED/INTER FIX RP THREADED/PERIMETER INTERBODY FUSION DEVICE, CLYDESDALE SPINAL SYSTEM	MEDTRONIC SOFAMOR DANEK USA, INC.	Site change for a manufacturing supplier.
P010012/S428	08/02/2016	X - 30-Day Notice	ACUITY X4 STRAIGHT, SPIRAL, SPIRAL L ; DYNAGEN, INOGEN, ORIGEN CRT-D'S	BOSTON SCIENTIFIC CORP.	Changes to the molding manufacturing line.
P010012/S429	08/01/2016	X - 30-Day Notice	DYNAGEN CRT-D: G150, G151, G154; DYNAGEN X4 CRT-D: G156, G158; INOGEN CRT-D: G140, G141; INOGEN X4 CRT-D: G146, G148; ORIGEN CRT-D: G050, G051; ORIGEN X4 CRT-D: G056, G058	BOSTON SCIENTIFIC CORP.	Alternate supplier of the titanium raw material used for capacitor can manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S306	08/16/2016	X - 30-Day Notice	CONSULTA CRT-P C4TR01; SYNCRA CRT-P C2TR01; VIVA CRT-P C6TR01	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks 9.2 at the Medtronic Tempe Campus.
P010030/S079	08/03/2016	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR (WCD) 4000	ZOLL MANUFACTURING CORPORATION	Use of an intermediate supplier to purchase device components and supply them to ZOLL.
P010031/S558	08/16/2016	X - 30-Day Notice	AMPLIA MRI CRT-D DTMB1D4; AMPLIA MRI QUAD CRT-D DTMB1QQ; BRAVA CRT-D DTBC1D4, DTBC1D1; BRAVA QUAD CRT-D DTBC1Q1, DTBC1QQ; COMPIA MRI CRT-D DTMC1D4; COMPIA MRI QUAD CRT-D DTMC1QQ; CONCERTO II CRT-D D274TRK; CONSULTA CRT-D D204TRM, D224TRK; MAXIMO II CRT-D D264TRM, D284TRK; PROTECTA CRT-D D334TRM, D334TRG; PROTECTA XT CRT-D D314TRM, D314TRG; VIVA QUAD S CRT-D DTBB1Q1, DTBB1QQ; VIVA QUAD XT CRT-D DTBA1Q1, DTBA1QQ; VIVA S CRT-D DTBB1D1, DTBB1D4; VIVA XT CRT-D DTBA1D1, DTBA1D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system to FACTORYworks 9.2 at the Medtronic Tempe Campus.
P010033/S029	08/19/2016	X - 30-Day Notice	QUANTIFERON-TB GOLD AND TB GOLD TEST (REFERENCE LAB PACK)	QIAGEN	Addition of two alternate suppliers for a raw material used to produce a critical assay component.
P010033/S030	08/25/2016	X - 30-Day Notice	QUANTIFERON-TB GOLD AND TB GOLD- TEST (REFERENCE LAB PACK)	QIAGEN	Changes to the sampling plan for the final release testing and removal of a testing specification.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010047/S043	08/17/2016	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Addition of a particulate matter quality checks at various stages of the Progel manufacturing process.
P020009/S128	08/10/2016	X - 30-Day Notice	EXPRESS 2 MR & OTW	BOSTON SCIENTIFIC SCIMED, INC.	Sterilize the devices with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P020024/S046	08/04/2016	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND AMPLATZER DUCT OCCLUDER II	AGA MEDICAL CORP.	Change to the pre-sterilization bioburden action and alert levels.
P020025/S090	08/11/2016	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Sterilize the devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P020027/S024	08/30/2016	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE (RF452)	SIEMENS HEALTHCARE DIAGNOSTICS	Add a filtration step in the Chrome Particle Raw Material (CPRM) manufacturing process.
P030005/S139	08/02/2016	X - 30-Day Notice	VALITUDE CRT-P	GUIDANT CORP.	Changes to the molding manufacturing line.
P030005/S140	08/10/2016	X - 30-Day Notice	VALITUDE CRT-P, ACCOLADE CRT-P	GUIDANT CORP.	Changes to an acceptance limit and sampling rate during battery testing.
P030009/S088	08/10/2016	X - 30-Day Notice	INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Implement an electronic laboratory management system.
P030035/S148	08/19/2016	X - 30-Day Notice	ALLURE, ALLURE RF, ALLURE QUADRA, ALLURE QUADRA RF - PM3120, PM3222, PM3140, PM3242	ST. JUDE MEDICAL, INC.	Alternate supplier of pacemaker case halves.
P030036/S086	08/15/2016	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change in supplier for a molded component used in lead manufacturing.

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P030054/S308	08/01/2016	X - 30-Day Notice	QUARTET CRT LEADS	St. Jude Medical	Assembly and inspection process changes during lead manufacturing.
P040024/S091	08/15/2016	X - 30-Day Notice	RESTYLANE / PERLANE INJECTABLE GEL	Q-MED AB	Change in the manufacturing site of 0.9% sodium chloride (NaCl)-solution.
P040040/S029	08/04/2016	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ST. JUDE MEDICAL CARDIOVASCULAR DIVISION	Change to the pre-sterilization bioburden action and alert levels.
P040043/S086	08/18/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implement the use of new raw material resins for use in Conformable TAG Thoracic (CTAG) catheter components.
P050006/S051	08/23/2016	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Add a new fixture for drying catheters following application of the HLC.
P050019/S025	08/10/2016	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Vendor changes for a resin used in the manufacturing of the stent delivery catheters.
P050028/S052	08/04/2016	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.
P050028/S053	08/18/2016	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST AND COBAS TAQMAN HBV TEST FOR USER WITH THE HIGH PURE SYSTEM	ROCHE MOLECULAR SYSTEMS, INC.	Change in resin used to manufacture a plastic consumable used with the device.
P060006/S076	08/10/2016	X - 30-Day Notice	EXPRESS SD RENAL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Vendor changes for a resin used in the manufacturing of the stent delivery catheters.
P060006/S077	08/11/2016	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P060006/S078	08/30/2016	X - 30-Day Notice	EXPRESS SD RENAL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Supplier site change.

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P060011/S010	08/19/2016	X - 30-Day Notice	C-FLEX MODEL 570C, C-FLEX ASPHERIC 970C AND 600 C ASPHERIC	RAYNER INTRAOCULA R LENSES LTD.	Change the final stage of the tumble polish process for C-flex 570C, C-flex Aspheric 970C and 600C Aspheric Intraocular Lenses.
P060018/S005	08/11/2016	X - 30-Day Notice	PRESTIGE CERVICAL DISC SYSTEM	MEDTRONIC SOFAMOR DANEK, INC.	Site change for a manufacturing supplier.
P060023/S005	08/11/2016	X - 30-Day Notice	BRYAN CERVICAL DISC SYSTEM	MEDTRONIC SOFAMOR DANEK USA, INC.	Site change for a manufacturing supplier.
P060027/S081	08/09/2016	X - 30-Day Notice	PLATINIUM CRT-D 1711/1741	SORIN GROUP CRM USA, INC	Add a second sterilizer for Platinium devices.
P060027/S082	08/08/2016	X - 30-Day Notice	PLATINIUM CRT-D 1711; PLATINIUM CRT-D 1741	SORIN GROUP CRM USA, INC	Use of the Automated Optical Inspection equipment during the microelectronic and electronic assembly manufacturing.
P060030/S052	08/04/2016	X - 30-Day Notice	COBAS TAQMAN HCV	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.
P060030/S053	08/18/2016	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change in resin used to manufacture a plastic consumable used with the device.
P070027/S047	08/10/2016	X - 30-Day Notice	TALENT OCCLUDER W OCCLUDER DELIVERY SYSTEM	MEDTRONIC VASCULAR	Implement an electronic laboratory management system.
P080012/S035	08/31/2016	X - 30-Day Notice	PROMETRA PROGRAMMABLE IMPLANTABLE PUMP	FLOWONIX MEDICAL, INC.	Inspection fixtures, inspection set-up, and manufacturing fixture changes used for verifying and assembling the Prometra and Prometra II pumps.
P080025/S117	08/22/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Changes to the manufacturing execution system (FACTORYworks) for Business Rule Client 9.2, Configuration Client 9.2, and Integrated Manufacturing Process Management Web Services 3.1.0.
P080025/S118	08/31/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM FOR BOWEL CONTROL	MEDTRONIC NEUROMODULATION	Alternate printed wiring board for use in hybrid manufacturing.
P090006/S018	08/10/2016	X - 30-Day Notice	COMPLETE SE VASCULAR STENT SYSTEM ILIAC	MEDTRONIC VASCULAR	Implement an electronic laboratory management system.

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P090013/S232	08/16/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG RVDR01	MEDTRONIC, INC	Update the manufacturing execution system to FACTORYworks 9.2 at the Medtronic Tempe Campus.
P090029/S005	08/11/2016	X - 30-Day Notice	PRESTIGE LP CERVICAL DISC SYSTEM	MEDTRONIC SOFAMOR DANEK USA, INC.	Site change for a manufacturing supplier.
P100020/S020	08/05/2016	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.
P100021/S055	08/10/2016	X - 30-Day Notice	MEDTRONIC ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implement an electronic laboratory management system.
P100040/S027	08/10/2016	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM W/ THE CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Implement an electronic laboratory management system.
P100045/S010	08/30/2016	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	St. Jude Medical	Implementation of an automated system for environmental monitoring in production areas.
P100047/S078	08/18/2016	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Implementation of a manufacturing change for a component of the DC Power Adapter.
P110004/S019	08/23/2016	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Update to the stent rinsing step.
P110004/S020	08/25/2016	X - 30-Day Notice	NIRXCELL COCR CORNARY STENT ON RX SYSTEM	MEDINOL LTD.	Update to the stent weighing process.
P110010/S128	08/10/2016	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Software change to the platinum chromium alloy (PCA) wetline used for production of uncoated stent components at the Galway, Ireland; Plymouth, Minnesota; and Maple Grove, Minnesota facilities.
P110010/S129	08/10/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.

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P110010/S130	08/18/2016	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the software used on the Automated Catheter Manufacturing Line Distal and Port Load and Unload stations in Galway.
P110010/S131	08/19/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replace the current aluminum layer in the poly/foil laminate packaging with a different aluminum alloy.
P110010/S132	08/29/2016	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Transfer a stent polishing line from the Boston Scientific Corporation (BSC) Plymouth facility to the BSC Maple Grove facility.
P110011/S012	08/10/2016	X - 30-Day Notice	ASSURANT COBALT ILIAC BALLOON-EXPANDABLE STENT SYSTEM	MEDTRONIC IRELAND	Implement an electronic laboratory management system.
P110013/S074	08/10/2016	X - 30-Day Notice	RESOLUTE INTEGRITY CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implement an electronic laboratory management system.
P110020/S017	08/04/2016	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Equipment change.
P110023/S020	08/02/2016	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM ,EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEM	MEDTRONIC VASCULAR INC	Addition of new stent processing equipment.
P110035/S037	08/30/2016	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Supplier site change.
P110037/S027	08/04/2016	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.

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P110037/S028	08/18/2016	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Change in resin used to manufacture a plastic consumable used with the device.
P110040/S010	08/10/2016	X - 30-Day Notice	MEDTRONIC VASCULAR COMPLETE SE VASCULAR STENT SYSTEM SFA AND PPA	MEDTRONIC VASCULAR	Implement an electronic laboratory management system.
P110042/S061	08/02/2016	X - 30-Day Notice	EMBLEM S-ICD SYSTEM	Boston Scientific Corporation	Changes to the molding manufacturing line.
P120005/S051	08/12/2016	X - 30-Day Notice	G4 PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM/ DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Extending the temperature excursion period for the Dexcom G5 Mobile/G4 PLATINUM Sensor. The proposed change seeks to extend the allowable temperature excursion period for the sensor component in its primary packaging. The Dexcom G5 Mobile/G4 PLATINUM Sensor is a component of the Dexcom G5 Mobile and the Dexcom G4 Platinum Continuous Glucose Monitoring System, respectively.
P120005/S052	08/25/2016	X - 30-Day Notice	G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Addition of G4 PLATINUM Transmitter manufacturing space. The G4 PLATINUM Transmitter is a component of the G4 PLATINUM Continuous Glucose Monitoring System.
P120006/S025	08/17/2016	X - 30-Day Notice	OVATION ABDOMINAL STENT GRAFT SYSTEM PLATFORM	TRIVASCULAR INC	Implementation of a revised welding program and modification to the weld flange orientation which is used in the manufacturing of the Ovation Abdominal Stent Graft System.
P120006/S026	08/24/2016	X - 30-Day Notice	OVATION ABDOMINAL STENT GRAFT SYSTEM PLATFORM	TRIVASCULAR INC	Implementation of an update to the iliac stent graft sheath loading fixture configuration and a revision to the corresponding loading process instructions to include the updated fixture configuration; 2) Implementation of the modified maximum loading force specification and in-sheath force specification of the Ovation iX Iliac Limb Stent Graft; and 3) Implementation of the modified crimp diameter for the 14 mm Ovation iX Iliac Stent Graft.
P120010/S092	08/15/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Additional plasma equipment used during manufacture of the Enlite sensor component at the Medtronic¿s sensor substrate supplier, Metrigraphics LLC.

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P120010/S093	08/25/2016	X - 30-Day Notice	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Add a new testing station to conduct a Manual Bolus Time Test (BTT) in the manufacturing process of the Paradigm Real-Time Insulin Pumps, Paradigm Real-Time Revel Pumps, and MiniMed 530G Insulin Pumps. These pumps are components of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and MiniMed 530G System, respectively. The testing station will be added to the manufacturing facility, located at Juncos, Puerto Rico.
P120019/S010	08/04/2016	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Equipment change.
P130007/S018	08/24/2016	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Modify the cartridge leak test process for the Animas Vibe Insulin Pump, from a manual leak test to an automated leak test. The Animas Vibe Insulin Pump is a component of the Animas Vibe System.
P130008/S014	08/03/2016	X - 30-Day Notice	INSPIRE II IMPLANTABLE PULSE GENERATOR	INSPIRE MEDICAL SYSTEMS	Implementation of additional peel strength testing for the Model 3024 Implantable Pulse Generator (IPG) at the contract manufacturer Medtronic MPROC Juncos Puerto Rico.
P130016/S020	08/24/2016	X - 30-Day Notice	NUCLEUS 24 HYBRID SYSTEM	COCHLEAR AMERICAS	Addition of an alternate PCB supplier for sound processor coils.
P130021/S023	08/10/2016	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM AND MEDTRONIC COREVALVE EVOLUT R SYSTEM	MEDTRONIC COREVALVE LLC	Implement an electronic laboratory management system.
P130026/S021	08/03/2016	X - 30-Day Notice	TACTICATH QUARTZ SET	St. Jude Medical	Addition of an alternate supplier for proximal fiber optic components.
P130028/S011	08/12/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Addition of 1) supplemental functional inspection; and 2) regular monitoring process of non-implantable electronic devices with integral batteries.
P130028/S012	08/19/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Changes to update the battery manufacturing equipment and addition of an alternate supplier for a wire battery component.
P130030/S025	08/10/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL & OTW	BOSTON SCIENTIFIC CORP.	Software change to the platinum chromium alloy (PCA) wetline used for production of uncoated stent components at the Galway, Ireland; Plymouth, Minnesota; and Maple Grove, Minnesota facilities.

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P130030/S026	08/10/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Sterilize the devices with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P130030/S027	08/29/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Transfer a stent polishing line from the Boston Scientific Corporation (BSC) Plymouth facility to the BSC Maple Grove facility.
P130030/S028	08/30/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Supplier site change.
P140010/S021	08/10/2016	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Implement an electronic laboratory management system.
P140010/S022	08/04/2016	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED BALLOON CATHETER	MEDTRONIC INC.	Alternate incoming inspection method to determine the API identity.
P140018/S003	08/21/2016	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implementation of a new drying oven used to remove moisture from the raw material.
P140023/S006	08/04/2016	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Equipment change.
P140028/S015	08/09/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Changes to the stent processing.

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P140031/S020	08/23/2016	X - 30-Day Notice	EDWARDS CRIMPER	EDWARDS LIFESCIENCES, LLC.	Addition of the Draper, UT facility as an alternate manufacturing site for the Edwards Crimper.
P150003/S016	08/10/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING CORONARY STENT SYSTEM	Boston Scientific Corporation	Software change to the platinum chromium alloy (PCA) wetline used for production of uncoated stent components at the Galway, Ireland; Plymouth, Minnesota; and Maple Grove, Minnesota facilities.
P150003/S017	08/18/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Update to the software used on the Automated Catheter Manufacturing Line Distal and Port Load and Unload stations in Galway.
P150003/S018	08/19/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Replace the current aluminum layer in the poly/foil laminate packaging with a different aluminum alloy.
P150003/S019	08/29/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Transfer a stent polishing line from the Boston Scientific Corporation (BSC) Plymouth facility to the BSC Maple Grove facility.
P150004/S004	08/18/2016	X - 30-Day Notice	AXIUM SHEATHS	SPINAL MODULATION, INC	Addition of an alternate supplier for a sub-assembly of the delivery sheaths used with the Axium Neurostimulator System.
P150005/S009	08/11/2016	X - 30-Day Notice	BLAZER OPEN-IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Sterilize the devices within the scope of this bundled submission with the optimized BSC2000-2 cycle in Chamber 5 and Chamber 7 at BSC Coventry, Rhode Island.
P150005/S010	08/19/2016	X - 30-Day Notice	BLAZER OI; INTELLANAV OI	BOSTON SCIENTIFIC CORP.	Addition of alternate vendors for manufacturing components for the Chilli II, Blazer OI, and IntellaNav OI Temperature Ablation Catheters.
P150012/S011	08/02/2016	X - 30-Day Notice	ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI PACEMAKER'S	BOSTONSCIENTIFIC	Changes to the molding manufacturing line.
P150012/S012	08/11/2016	X - 30-Day Notice	INGEVITY ACTIVE FIXATION LEAD	BOSTONSCIENTIFIC	Simplify the distal tip subassemblies for finished drug product testing.
P150014/S003	08/04/2016	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.

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P150015/S003	08/04/2016	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Addition of a new fermenter used in the manufacturing process for enzymes.
P150017/S001	08/25/2016	X - 30-Day Notice	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Change the vendor that supplies the foil lidstock used to seal the primary packaging of the Cartiva SCI device.
P150019/S017	08/15/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Additional plasma equipment used during manufacture of the Enlite sensor component at the Medtronic¿s sensor substrate supplier, Metrigraphics LLC.
P150019/S018	08/25/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL INSULIN SYSTEM	MEDTRONIC MINIMED	Add a new testing station to conduct a Manual Bolus Time Test (BTT) in the manufacturing process of the Paradigm Real-Time Insulin Pumps, Paradigm Real-Time Revel Pumps, and MiniMed 530G Insulin Pumps. These pumps are components of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and MiniMed 530G System, respectively. The testing station will be added to the manufacturing facility, located at Juncos, Puerto Rico.
P150029/S001	08/15/2016	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Additional plasma equipment used during manufacture of the Enlite sensor component at the Medtronic¿s sensor substrate supplier, Metrigraphics LLC.
P150033/S005	08/16/2016	X - 30-Day Notice	MICRA TPS MC1VR01	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYworks 9.2 at the Medtronic Tempe Campus.
P150033/S006	08/15/2016	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Implementation of a laboratory information management system in the microbiology lab.

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